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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,677	10/06/2004	Mark Parrington	API-01-20-US	4967
7590	04/21/2008		EXAMINER	
Patrick J Halloran Aventis Pasteur Inc Intellectual Property Kenerr Bldg One Discovery Drive Swiftwater, PA 18370			AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	
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			04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,677	PARRINGTON ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 February 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30 and 36-50 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/11/08</u> . | 6) <input type="checkbox"/> Other: _____ . |

Detailed Action

Election/Restriction

The Election filed 2/11/08 in response to the Office Action of 1/9/08 is acknowledged and has been entered. Applicant elected group I with traverse. Applicant further elected the following species with traverse: ALVAC poxvirus vector.

The traversal is on the ground(s) that amended claim 1 indicates that the claimed expression vector must allow for expression of a CEA protein. Applicant further states that the claimed expression vector represents a significant contribution over the prior art. Applicant further argues that all of the claims require SEQ ID NO:28 or a fragment thereof and if SEQ ID NO:28 or fragments thereof represent patentable subject matter additional searches relating to particular vectors will not be required. This is not found persuasive. The inventions listed as groups I-II in the Office Action of 1/9/08 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking groups I-II appears to be that they all relate to the special technical feature of an expression vector comprising SEQ ID NO:28 or a fragment thereof. However, as discussed below, Paoletti et al (US Patent 5,833,975; 11/10/98) teaches an expression vector comprising a fragment of SEQ ID NO:28 that expresses a CEA protein (see abstract, in particular). Therefore, the technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, groups I-II are not so linked by the same or a corresponding

special technical feature as to form a single general inventive concept. Further, in regards to the argument that if SEQ ID NO:28 or fragments thereof represent patentable subject matter additional searches relating to particular vectors will not be required, claimed products comprising fragments of SEQ ID NO:28 do not represent patentable subject matter. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-30 and 36-50 are pending and are currently under consideration.

Specification

The specification is objected to for improper disclosure of polypeptide sequences (see page 15, in particular), as it fails to comply with the requirements of 37 CFR 1.821 through 1.825. This definition sets forth limits, in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. (see MPEP 2422). Proper correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 and 36-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of: **(1)** a genus of nucleic acids comprising fragments of SEQ ID NO:28 (see claim 1, for example), **(2)** a genus of nucleic acid molecules comprising nucleotides 421-1490 of SEQ ID NO:28 (see claim 45, for example), and **(3)** a genus of compositions comprising nucleic acid molecules “of” nucleic acid molecules comprising nucleotides 421-1490 of SEQ ID NO:28 (see claim 50). It is noted that a genus of nucleic acids comprising fragments of SEQ ID NO:28 includes nearly every imaginable polynucleotide, as fragments of SEQ ID NO:28 include single nucleotides. Further, claims drawn to nucleic acid molecules comprising fragments of SEQ ID NO:28 “including at least nucleotides 421-1490” (see claim 45) do not require that said fragments comprise *the* sequence set-forth as nucleotides 421-1490 of SEQ ID NO:28. Said claims do not require any particular order of nucleotides 421-1490. Rather, said claims encompass nucleic acid molecules comprising nucleotides 421-1490 *in any order*. Further, claims drawn to compositions comprising “an” isolated nucleic acid molecule of a polynucleotide (see claim 50) encompass compositions comprising any fragment of said polynucleotide, as fragments of said polynucleotides are nucleic acid molecules of said polynucleotides.

The written description in this case sets forth polynucleotides comprising *the* sequence set-forth in SEQ ID NO:28, polynucleotides comprising *the* sequence set-forth as nucleotides 421-1490 of SEQ ID NO:28, compositions comprising polynucleotides comprising *the* sequence set-forth in SEQ ID NO:28, and compositions comprising polynucleotides comprising *the* sequence set-forth as nucleotides 421-1490 of SEQ ID NO:28. The specification does not disclose, and the art does not teach the broad genera of variants as broadly encompassed by the claims.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genera. That is, the specification provides neither a representative number of nucleic acids that encompass the genera nor does it provide a description of

structural features that are common to the genera. Since the disclosure fails to describe common attributes or characteristics that identify members of the genera, and because the genera are highly variant, the disclosure of SEQ ID NO:28 is insufficient to describe the genera. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genera, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification

provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-30 and 36-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al (US Patent 5,833,975; 11/10/98).

The claims are drawn to expression vectors comprising the nucleic acid sequence set-forth in SEQ ID NO:28 or fragments thereof.

Paoletti et al teaches ALVAC poxvirus vectors comprising SEQ ID NO:145, which comprises fragments of nucleic acids 421-1490 of SEQ ID NO:28 (see abstract and sequence comparison below, in particular). Paoletti et al further teaches said vectors further comprising additional tumor-associated antigens (see abstract, in particular), nucleic acid sequences encoding angiogenesis associated antigens (see EGFR at lines 1-15 of column 15, in particular), and nucleic acid sequences including the costimulatory molecule B7.1 (line 58 of column 14, in particular). Paoletti et al further teaches compositions comprising said vectors and pharmaceutically acceptable carriers (see

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line 22 of column 8, in particular). It is further noted that the nucleic acids of SEQ ID NO:145 includes all nucleic acids of 421-1490 of SEQ ID NO:28 (A, T, G, and C).

Comparison of instant SEQ ID NO:28 and SEQ ID NO:145 of Paoletti et al:

Query Match 80.6%; Score 1697.8; DB 2; Length 2349;
Best Local Similarity 88.1%; Pred. No. 0;
Matches 1859; Conservative 0; Mismatches 247; Indels 3; Gaps 1;

Qy 1 ATGGAGTCTCCCTCGGCCCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGCTC 60
Db 184 ATGGAGTCTCCCTCGGCCCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGCTC
243

Qy 61 ACAGCCTCACTTCTAACCTTCTGGAACCCGCCACCCTGCCAAGCTCACTATTGAATCC
120
Db 244 ACAGCCTCACTTCTAACCTTCTGGAACCCGCCACCCTGCCAAGCTCACTATTGAATCC
303

Qy 121 ACGCCGTTCAATGTCGCAGAGGGAAAGGAGGTGCTTCTACTTGTCCACAATCTGCCAG
180
Db 304 ACGCCGTTCAATGTCGCAGAGGGAAAGGAGGTGCTTCTACTTGTCCACAATCTGCCAG
363

Qy 181 CATCTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
240
Db 364 CATCTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
423

Qy 241 GGATATGTAATAGGAACTCAACAAGCTACCCAGGGCCCGCATACAGTGGTCGAGAGATA
300
Db 424 GGATATGTAATAGGAACTCAACAAGCTACCCAGGGCCCGCATACAGTGGTCGAGAGATA
483

Qy 301 ATATAACCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAATGACACAGGATTCTAC
360
Db 484 ATATAACCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAATGACACAGGATTCTAC
543

Qy 361 ACCCTACACGTCTAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGGTA
420
Db 484 ACCCTACACGTCTAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGGTA
543

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Db 1143	1084	GCCCATAACTCAGACACTGGCCTCAATAGGACCACAGTCACGACGATCACAGTCTATGCA
Qy 1017	958	GAGCCACCAAAACCATTCTAACAATTCTAACCCAGTTGAGGATGAGGACGCA
Db 1203	1144	GAGCCACCCAAACCCTCATCACCAAGCAACAACCTCCAACCCGTGGAGGATGAGGATGCT
Qy 1077	1018	GTTCATTAACCTGTGAGCCAGAGATTCAAAATACCACTTATTATGGTGGTCAATAAC
Db 1263	1204	GTAGCCTAACCTGTGAACCTGAGATTCAAGAACACAACCTACCTGTGGTGGTAAATAAT
Qy 1137	1078	CAAAGTTGCCGGTTAGCCCACGCTTGCAGTTCTAATGATAACCGCACATTGACACTC
Db 1323	1264	CAGAGCCTCCCGGTCAAGTCCCAGGCTGCAGCTGTCCAATGACAACAGGACCCTCACTCTA
Qy 1197	1138	CTGTCCGTTACTCGCAATGATGTAGGACCTATGAGTGTGGCATTCAAATGAATTATCC
Db 1383	1324	CTCAGTGTACAAGGAATGATGTAGGACCTATGAGTGTGGAACCTCAGAACGAATTAAGT
Qy 1257	1198	GTTGATCACTCCGACCCGTATCCTTAATGTTTGATGGCCAGACGACCCAACATA
Db 1443	1384	GTTGACCACAGCGACCCAGTCATCCTGAATGTCCTCTATGGCCAGACGACCCCCACCATT
Qy 1317	1258	TCTCCATCATACACCTACTACCGTCCCAGGTGAACCTGAGCCTTCTGCCATGCAGCA
Db 1503	1444	TCCCCCTCATACACCTATTACCGTCCAGGGGTGAACCTCAGCCTCTCTGCCATGCAGCC
Qy 1377	1318	TCCAACCCCCCTGCACAGTACTCCTGGCTGATTGATGGAAACATTCAGCAGCATACTCAA
Db 1563	1504	TCTAACCCACCTGCACAGTATTCTGGCTGATTGATGGAAACATCCAGCAACACACACAA
Qy 1437	1378	GAGTTATTATAAGCAACATAACTGAGAAGAACAGCGGACTCTATACTTGCCAGGCCAAT
Db 1623	1564	GAGCTCTTATCTCCAACATCACTGAGAAGAACAGCGGACTCTATACTGCCAGGCCAAT
Qy 1497	1438	AACTCAGCCAGTGGTCACAGCAGGACTACAGTTAAAACAATAACTGTTCCGGAGCTG

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Db 1683	1624 AACTCAGCCAGTGGCACAGCAGGACTACAGTCAAGACAATCACAGTCTCTGCGGAGCTG
Qy 1557	1498 CCCAAGCCCTCCATCTCCAGCAACAACCTCAAACCGTGGAGGACAAGGATGCTGTGGCC
Db 1743	1684 CCCAAGCCCTCCATCTCCAGCAACAACCTCAAACCGTGGAGGACAAGGATGCTGTGGCC
Qy 1617	1558 TTCACCTGTGAACCTGAGGCTCAGAACACAAACCTACCTGTGGTGGTAAATGGTCAGAGC
Db 1803	1744 TTCACCTGTGAACCTGAGGCTCAGAACACAAACCTACCTGTGGTGGTAAATGGTCAGAGC
Qy 1677	1618 CTCCCAGTCAGTCCCAGGCTGCAGCTGTCCAATGGCAACAGGACCCTCACTCTATTCAAT
Db 1863	1804 CTCCCAGTCAGTCCCAGGCTGCAGCTGTCCAATGGCAACAGGACCCTCACTCTATTCAAT
Qy 1737	1678 GTCACAAGAAATGACGCAAGAGCCTATGTATGTGGAATCCAGAACTCAGTGAGTGCAAC
Db 1923	1864 GTCACAAGAAATGACGCAAGAGCCTATGTATGTGGAATCCAGAACTCAGTGAGTGCAAC
Qy 1797	1738 CGCAGTGACCCAGTCACCCCTGGATGTCTCTATGGGCCGGACACCCCCATCATTTCCCCC
Db 1983	1924 CGCAGTGACCCAGTCACCCCTGGATGTCTCTATGGGCCGGACACCCCCATCATTTCCCCC
Qy 1857	1798 CCAGACTCGTCTTACCTTCGGAGCGGACCTCAACCTCTCCTGCCACTCGGCCTCTAAC
Db 2043	1984 CCAGACTCGTCTTACCTTCGGAGCGAACCTCAACCTCTCCTGCCACTCGGCCTCTAAC
Qy 1917	1858 CCATCCCCGAGTATTCTGGGTATCAATGGGATACCGCAGCAACACACACAAGTTCTC
Db 2103	2044 CCATCCCCGAGTATTCTGGGTATCAATGGGATACCGCAGCAACACACACAAGTTCTC
Qy 1977	1918 TTTATGCCAAAATCACGCCAATAATAACGGGACCTATGCCTGTTGTCTAACTTG
Db 2163	2104 TTTATGCCAAAATCACGCCAATAATAACGGGACCTATGCCTGTTGTCTAACTTG
Qy 2037	1978 GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGAACTTCT

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Db 2164 GCTACTGGCCGCAATAATTCCATAGTCAGAGCATCACAGTCTCTGCATCTGGAACCTCT
2223

Qy 2038 CCTGGTCTCTCAGCTGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGTTGCT
2097 |||||||

Db 2224 CCTGGTCTCTCAGCTGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGTTGCT
2283

Qy 2098 CTGATATAG 2106
|||

Db 2284 CTGATATAG 2292

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642